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June 27, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket N. 99N-4578

This letter is in response to the call for comments on proposed regulations controlling the State Certification of Mammography Facilities, published in the Federal Register on March 30, 2000. The American College of Radiology offers the following comments.

1. General

The path of dataflow between accreditation bodies and state certifying agencies is not specified in the regulation. We understand that it is the intent of the FDA to continue the current arrangement whereby data is provided directly to FDA and then made available by FDA to certifying states. We would like this to be specified as a part of the regulation.

2. 900.22(e) Appeals

We are concerned as to how appeals for failed clinical images will be handled by certifying states under this process. The clinical image review process within the ACR accreditation program is conducted by highly qualified and trained radiologists chosen nationwide. The appeals process within ACR is performed by the most experienced and expert of the reviewers. It seems unlikely that a particular state will have available reviewers of this caliber. Indeed, we use reviewers from a different geographical area to avoid regional bias and to maintain one national standard for image quality.

Certifying states, however, may find themselves in the position of overriding the judgment of our appeal reviewers. We would prefer a process where this situation did not arise, and would be happy to discuss how this might work.

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3. 900.22(f) Additional Mammography Review

We are concerned as to the criteria being used to initiate additional mammography review. It seems that the frequency of such review is markedly increasing. The final regulations state that the criterion should be '...mammography quality at a facility has been compromised and may present a serious risk to human health,...'. We believe this is the correct test, and would be happy to be a participant in the discussions that lead to such a decision.

Thank you for the opportunity to participate in this rulemaking process.

Sincerely,

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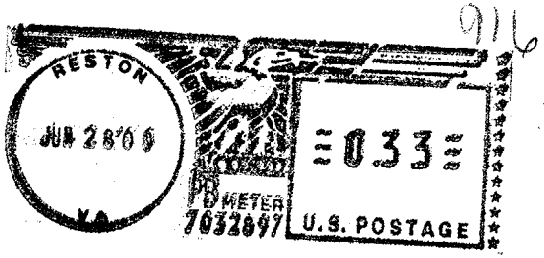

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